Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2004 list were published in the Federal Register in June 2004.

New Approvals

ANADA Number: 200-317

Pioneer Product:	104-606
Trade Name:	Dexium-SP™
Ingredients:	Dexamethasone sodium phosphate
Sponsor:	Cross Vetpharm Group Ltd.
Approval Date:	April 29, 2004
Status:	Prescription only
Route:	Intravenous
Species:	Horses
Drug Form:	Liquid (solution)
Concentration:	4 milligrams per milliliter (equivalent to 3 milligrams per milliliter dexamethasone)
Indications:	As a rapid glucocorticoid and/or anti-inflammatory agent

21CFR 522.540

ANADA Number: 200-356

Pioneer Product:	141-011
Trade Name:	Pennchlor™ & Denagard®
Ingredients:	Chlortetracycline hydrochloride, tiamulin hydrogen fumarate
Sponsor:	Pennfield Oil Co.
Approval Date:	April 6, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Swine
Drug Form:	Type A Medicated Articles to make Type B or C medicated feeds.
Concentration:	Chlortetracycline 50 - 100 grams activity per pound of Type A Medicated Article; tiamulin 10 grams activity per pound of Type A Medicated Article.
Indications:	For treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.
Tolerance:	21CFR 556.150 Chlortetracycline: A tolerance for the sum of residues of tetracycline in tissues of swine are as follows: 2 parts per million in muscle, 6 parts per million in liver, 12 parts per million in fat and kidneys. 21CFR 556.738 Tiamulin: A tolerance of 0.6 part per million is established for 8-alpha-hydroxymutilin (marker compound) in liver (target tissue).
Withdrawal:	2 days

21CFR 558.600

ANADA Number: 200-361

Pioneer Product:	015-030
Trade Name:	Acepromazine Maleate Injection
Ingredients:	Acepromazine maleate
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	April 14, 2004
Status:	Prescription only
Route:	Intravenous, intramuscular, or subcutaneous
Species:	Dogs, cats, and horses
Drug Form:	Liquid (solution)
Concentration:	10 milligrams per milliliter
Indications:	As a tranquilzer

21CFR 522.23

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-228

Trade Name:	Buscopan™ Injectable Solution
Ingredients:	N-butylscopolammonium bromide
Sponsor:	Boehringer Ingelheim Vetmedica, Inc.
Approval Date:	May 3, 2004
Status:	Prescription only
Route:	Intravenous
Species:	Horses
Drug Form:	Liquid (solution)
Concentration:	20 milligrams per milliliter
Indications:	For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.
Exclusivity:	5 years

21CFR 522.275

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 140-833

This supplemental application provides for an increased period of protection from reinfection with three species of internal parasites, *Oesophagostomum radiatum* for 28 days after treatment and *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment. Additionally, the labeling is being revised to update the environmental information and a veal calf warning statement is being added.

Trade Name:	Ivomec® Plus Injection for Cattle
Ingredients:	Ivermectin, clorsulon
Sponsor:	Merial Limited
Approval Date:	April 21, 2004
Status:	Over-the-counter
Route:	Subcutaneous
Species:	Cattle: beef, dairy not breeding age and excluding veal calves.
Drug Form	Liquid (solution)
Concentration:	Ivermectin 1% (10 milligrams per milliliter), clorsulon 10% (100 milligrams per milliliter).
Indications:	For the treatment and control of various species of gastrointestinal roundworms, lungworms, liver flukes, grubs, biting and sucking lice, and mange mites. Protects cattle against reinfection with: *Oesophagostomum radiatum* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment.
Tolerance:	*21CFR 556.344* Ivermectin: A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in liver (target tissue) as follows: cattle 100 parts per billion. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22,23-dihydroavermectin B_1a (marker residue) in muscle as follows: cattle 10 parts per billion.
Withdrawal:	49 days
Exclusivity:	3 years

21CFR 522.1193

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-193

This supplemental application provides for an expanded dose range up to 15 milligrams per pound and revised wording of the indications.

Trade Name:	Clindamycin Hydrochloride Oral Liquid
Ingredients:	Clindamycin hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	April 21, 2004
Status:	Prescription only
Route:	Oral
Species:	Dogs and cats
Drug Form:	Liquid
Concentration:	25 milligrams per milliliter
Indications:	**Dogs:** For the treatment of skin infections (wounds and abscess) due to coagulase positive staphylococci (*Staphylococcus aureus orS. Intermedius)*, deep wounds and abscess due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens*, dental infections due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens*, and osteomyelitis due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens*. **Cats:** For the treatment of skin infections (wounds and abscess) due to coagulase positive staphylococci (*Staphylococcus aureus orS. Intermedius), Streptococcus* spp., deep wounds and abscesses due to *Clostridium perfringens* and *Bacteroides fragilis,* and dental infections due to *S. aureus, S. intermedius, Streptococcus* spp., *C. perfringens*, and *B. fragilis*.

21CFR 520.447

ANADA Number: 200-298

This covers two separate supplemental applications. The two applications provide for an expanded dose range up to 15 milligrams per pound, revised wording of the indications, and a new 300 milligram capsule size.

Trade Name:	Clindamycin Hydrochloride Capsules
Ingredients:	Clindamycin hydrochloride
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	April 21, 2004
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Capsule
Concentration:	25, 75, 150, and 300 milligrams per capsule
Indications:	For the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed: Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *S. intermedius)*, deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum,* and *Clostridium perfringens,* dental infections due to *S. aureus, B. fragilis, P. melaninogenicus, F. necrophorum,* and *C. perfringens*.

21CFR 520.446

Change of Sponsor

NADA Number(s): 091-260 & 102-942

From:	Zema Corp.
To:	Virbac AH, Inc. 3200 Meacham Blvd. Ft. Worth, TX 76137
Drug labeler code:	051311

Actions Taken by FDA Center for Veterinary Medicine

Suitability Petition Action

Number:	04P-0130/WDL1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to withdraw request to file an ANADA for a generic new animal drug amoxicillin which differs from the pioneer product, Amoxi-Tabs®, Pfizer Inc., NADA 055-078 and NADA 055-081 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Acknowledged on May 21, 2004.

Number:	04P-0127/PRC1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission for reconsideration to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristic(s): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.
Action:	Filed on June 10, 2004.

Number:	04P-0197/CP1
Sponsor:	First Priority, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug gentamicin sulfate which differs from the pioneer product, Garacin®, Schering-Plough Animal Health, NADA 130-464 by the following characteristic(s): The generic product will have a change in strength of oral solution in a pump dispenser from 4.35 milligrams per milliliter to 4.77 milligrams per milliliter. The delivery volume would also change from 1.15 milliliter per pump to 1.05 milliliter per pump.
Action:	Approved on June 24, 2004.

Correction of a Final Rule

The Food and Drug Administration (FDA) is amending the animal drug regulations for oxytetracycline injectable solutions. The regulations for oxytetracycline injectable solutions are also being revised to conform to a current format. These changes are being made to improve the organization and readability of the regulations. In the Federal Register of September 19, 2003 (68 FR 54804), Section 522.1660a (21 CFR 522.1660a) was added to reflect the approval of a 300-milligrams/milliliter oxytetracycline injectable solution under NADA 141-143. At this time, we are redesignating and amending Sections 522.1660 (21 CFR 522.1660) (200 milligrams/milliliter) and 522.1660a as Sections 522.1660a and 522.1660b, respectively.

The Food and Drug Administration (FDA) is correcting a document that amended the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA 112-051) that appeared in the Federal Register of March 2, 2004 (69 FR 9753) which appeared in the Greenbook monthly supplement of April 2004. FDA is correcting the formatting of a citation of approved conditions of use for levamisole powder for oral solution in cattle. In Section 520.1242a, paragraph (b)(2), remove the reference ``(e)(1)(ii)(a)'' and add in its place ``(e)(1)(ii)(A)''. This correction is being made so the regulations accurately cite approved conditions of use of this animal drug product.